



Food and Drug Administration
10903 New Hampshire Avenue
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November 2, 2016

Fournitures Hospitalieres Industrie
Mr. Franck Hunt
General Manager
6 Rue Nobel, Z.I. de Kernevez
29000 Quimper
FRANCE

Re: K112193

Trade/Device Name: Arrow® Reverse Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, KWS, KWT
Dated: June 27, 2012
Received: July 3, 2012

Dear Mr. Hunt:

This letter corrects our substantially equivalent letter of July 12, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

Indications for Use

510(k) Number (if known): K112193

Device Name: ARROW® reverse shoulder system

Indications for Use: The ARROW® reverse shoulder prosthesis is indicated for patients with severe shoulder arthropathy and a grossly deficient rotator cuff or a previously failed shoulder joint replacement with a grossly deficient rotator cuff. A functional deltoid muscle and adequate glenoid bone stock are necessary to use this device. The humeral stem is intended for cemented or cementless application while the metal-back glenoid baseplate is intended for cementless application with the addition of bone screws for fixation.

Prescription Use ☒
(Part 21-CFR 801 Subpart D)

AND/OR

Over the counter Use ☐
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number

K112193

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Lori A. Wiggins -S

for

Mark N. Melkerson

Director

Division of Orthopedic Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

JUL 12 2012

5. 510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance to the requirements of SDMA 1990 and 21 CFR 807.92.

Date prepared: July 9th 2012

The assigned 510(k) number is: K112193

5-1. Applicant:

Fournitures Hospitalières industrie
6 Rue Nobel, Z.I. de Kernévez
29000 QUIMPER - FRANCE
Tel: (+33) 2.98.55.68.95
Fax: (+33) 2.98.53.42.13

5-2. Company Contact:

Franck HUNT, General Manager
Tel: (+33) 2.98.55.68.95

5-3. Product :

Trade name: ARROW® Reverse Shoulder System

Common name: Shoulder prosthesis

Classification: The ARROW® Reverse Shoulder System components are included in the following classifications :

- Shoulder joint metal/polymer semi-constrained cemented prosthesis
Product code: KWS
Regulation: 21 CFR 888.3660
Class: II
- Shoulder joint metal/polymer non-constrained cemented prosthesis
Product code: KWT
Regulation: 21 CFR 888.3650
Class: II

Fournitures Hospitalières industrie

ARROW® Reverse Shoulder system
Traditional 510(k) Premarket Notification**5-4. Predicate/ Legally Marketed Devices :**

Information on devices to which substantial equivalence is claimed:

Manufacturer:	Zimmer
Device Trade Name:	Anatomical Shoulder® Inverse/Reverse system
510 (K):	K053274
Manufacturer:	Exactech, Inc.
Device Trade Name:	Equinox™ Reverse Shoulder system
510 (K):	K073688/K063569
Manufacturer:	Depuy
Device Trade Name:	Delta Xtend™ Reverse Shoulder system
510 (K):	K062250
Manufacturer:	Fournitures Hospitalières Industrie
Device Trade Name:	ARROW® Anatomical shoulder system
510 (K):	K093599

5-5. Device Description:

The ARROW® reverse shoulder system is a shoulder joint prosthesis, composed of the following elements :

- Humeral stems,
- STD humeral inserts,
- Glenospheres
- Metal-back glenoid bases
- And fixation screws for the metal back glenoid base (cancellous and cortical bone screws)

The ARROW® reverse shoulder system is intended to be implanted using the dedicated instrumentation supplied by the manufacturer.

5-6. Indications for Use/ Intended Use:

The ARROW® reverse shoulder prosthesis is indicated for patients with severe shoulder arthropathy and a grossly deficient rotator cuff or a previously failed shoulder joint replacement with a grossly deficient rotator cuff. A functional deltoid muscle and adequate glenoid bone stock are necessary to use this device. The humeral stem is intended for cemented or cementless application while the metal-back glenoid baseplate is intended for cementless application with the addition of bone screws for fixation.

5-7. Comparison of Technological Characteristics:

The ARROW® reverse shoulder prosthesis and the above selected predicate devices have the same intended use and substantial similar indications for use and share the following similarities :

- They are made out of the same materials (titanium alloy for the humeral stem, the metal-back glenoid base and the fixation screws, cobalt chromium alloy for the glenosphere, polyethylene and titanium alloy for humeral insert),
- They are available in similar ranges of sizes,
- They bear design features similarities

5-8. Performances:

The ARROW® reverse shoulder prosthesis was tested according to ASTM F1378-05, ASTM F1829-98 for the glenoid components. After the testing was completed, it was determined that the ARROW® reverse shoulder system performances were substantially equivalent to those of the selected predicated devices.

Risks to health have been addressed through the specified materials, processing controls, quality assurance and compliance to the Medical Device Good Manufacturing Practices Regulations.

5-9. Substantial Equivalence:

The substantial equivalence of our product, when compared to the selected predicate devices, has been established following manufacturers' commercial documents, 510(k) submission's information available on FDA's website as well as conformance to standards in force.

The analysis of these technical data allows us to submit the ARROW® reverse shoulder prosthesis as being substantially equivalent to the already cleared predicate devices selected to a draw a comparison.

All data on predicate devices which has been used to establish equivalence is available in appendix 8.

5-10. Conclusion:

Following the examination of all the above mentioned information, we believe that the ARROW® reverse shoulder prosthesis is substantially equivalent to the selected predicate devices in terms of desing, ranges of sizes, materials, intended use, performances, safety and effectiveness.